

CANYON DIAGNOSTICS, INC.

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Center for Devices and Radiological Health
Food And Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

510(k) Submission Summary

This summary regarding the enclosed 510(k) submission is intended to support safety and effectiveness information in accordance with requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

CANTROL Iron /TIBC Controls provide a simple, but effective, method for the performance of intra- or inter- laboratory quality control in the quantitation of Serum Iron and Total Iron Binding Capacity.

CANTROL Iron/TIBC Controls are manufactured from human serum and provide a means for monitoring Serum Iron and TIBC testing procedures by the use of control materials in a manner identical to patient samples. CANTROL Iron/TIBC Control materials are equivalent to other human serum based chemistry control products.

Testing of CANTROL Iron/TIBC Control material was accomplished to demonstrate short term and long term product stability. Short term stability was demonstrated by real time product storage. Long term stability was conducted by an accelerated testing protocol as described in the submission data.

Product precision performance was demonstrated through replicate analyses in the conductance during stability testing.

Submitted by:

Date:

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